

OPEN HEARING

STATEMENTS FROM EPITOPE

STATEMENTS FROM AABB

Indeterminate Non-viral Band Blots for HIV-1
FDA Blood Products Advisory Committee Meeting

March 16, 2000

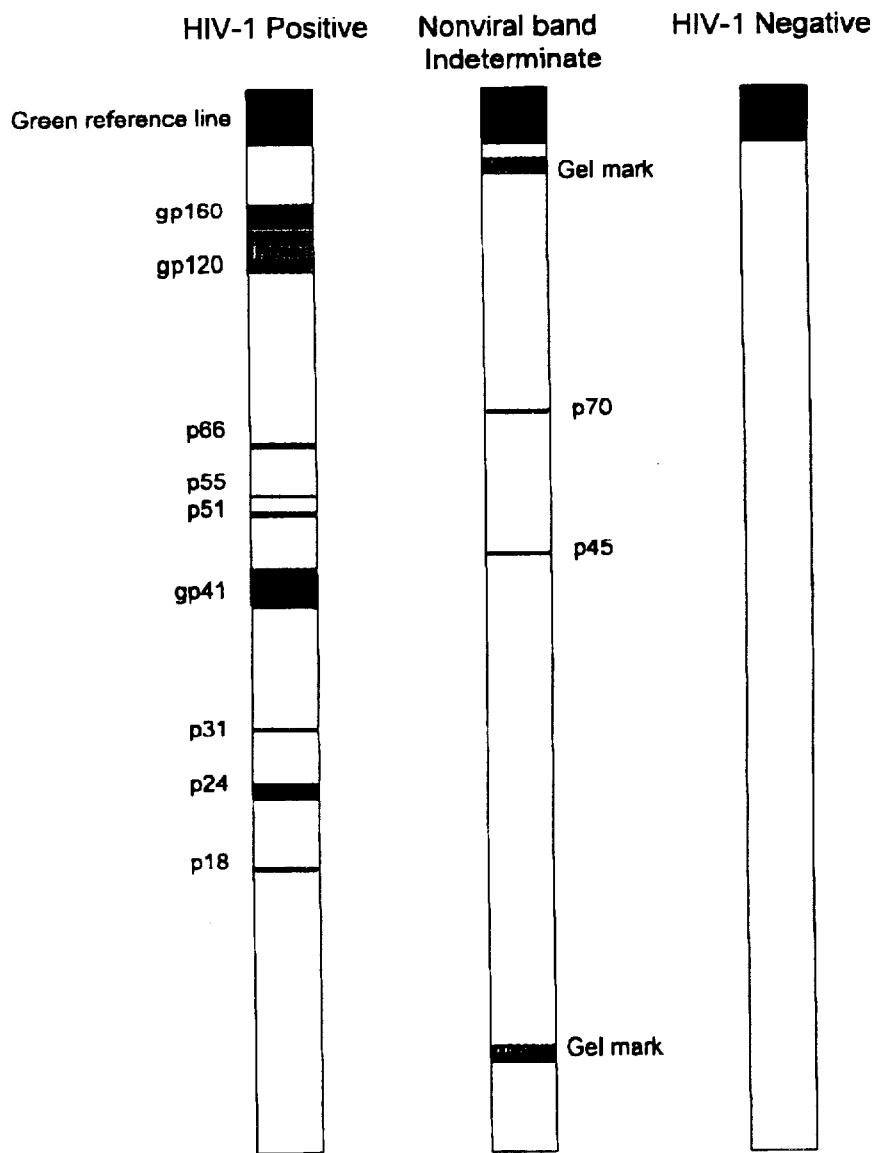
**Epitope, Inc.
Beaverton, Oregon 97008**

Nonviral Bands on Epitope's Western Blots

- Epitope manufactures two Western Blot assays for different body fluids
 - Serum/plasma
 - OraSure oral fluid
- Epitope's Western blot assays are distributed by Organon Teknika Corporation
- HIV Western blot assays prepared from viral lysates contain cellular antigens (e.g., HLA, actin)
- Nonviral bands on Epitope's Western blots usually appear in two locations
 - p70
 - p45
- Epitope Western blot assays can show two additional "pseudo-bands"
 - Gel edge mark near green reference line
 - Gel edge mark near bottom of strip
- Epitope Western blot nonviral bands do not react with anti-gag, anti-pol, or anti-env monoclonal antibodies

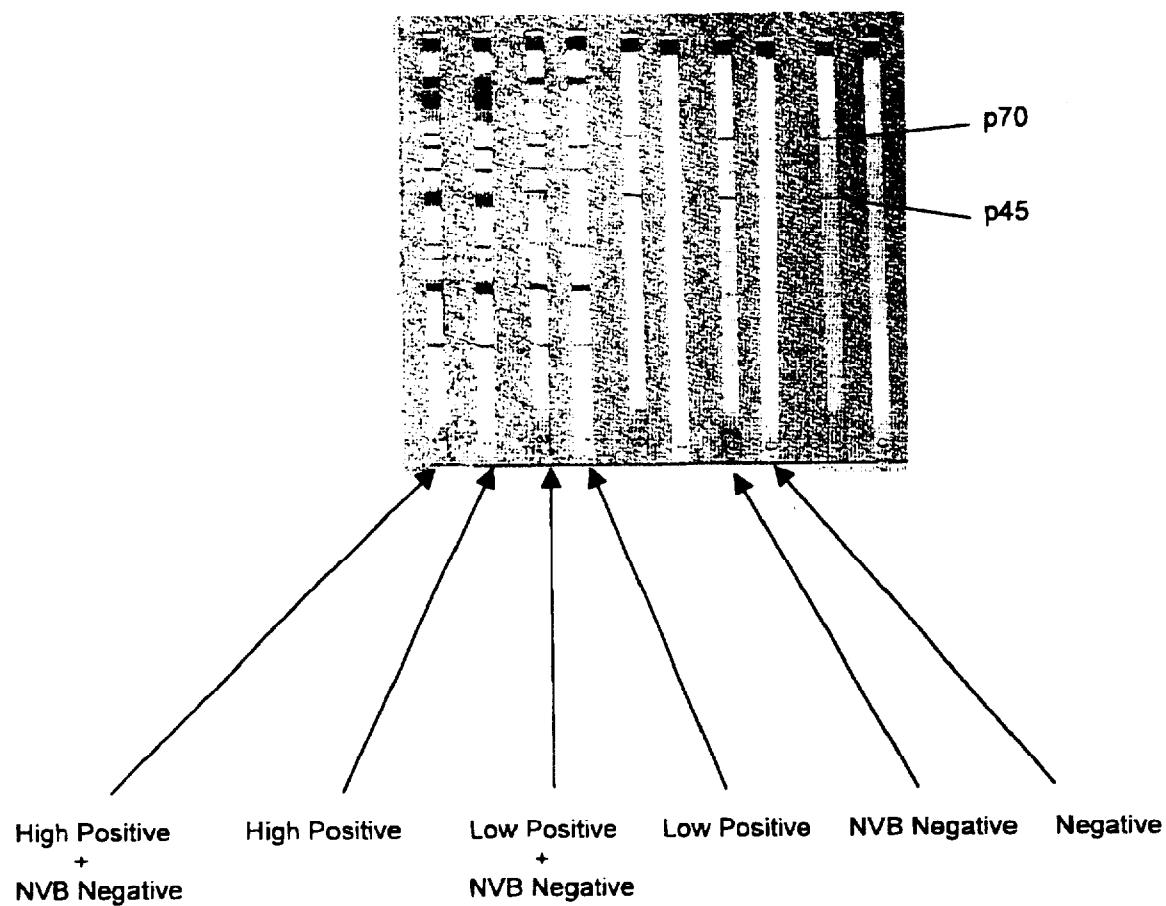
FDA BPAC meeting March 16, 2000
Western blot nonviral bands
Epitope, Inc. Beaverton, OR

Epitope Western Blot



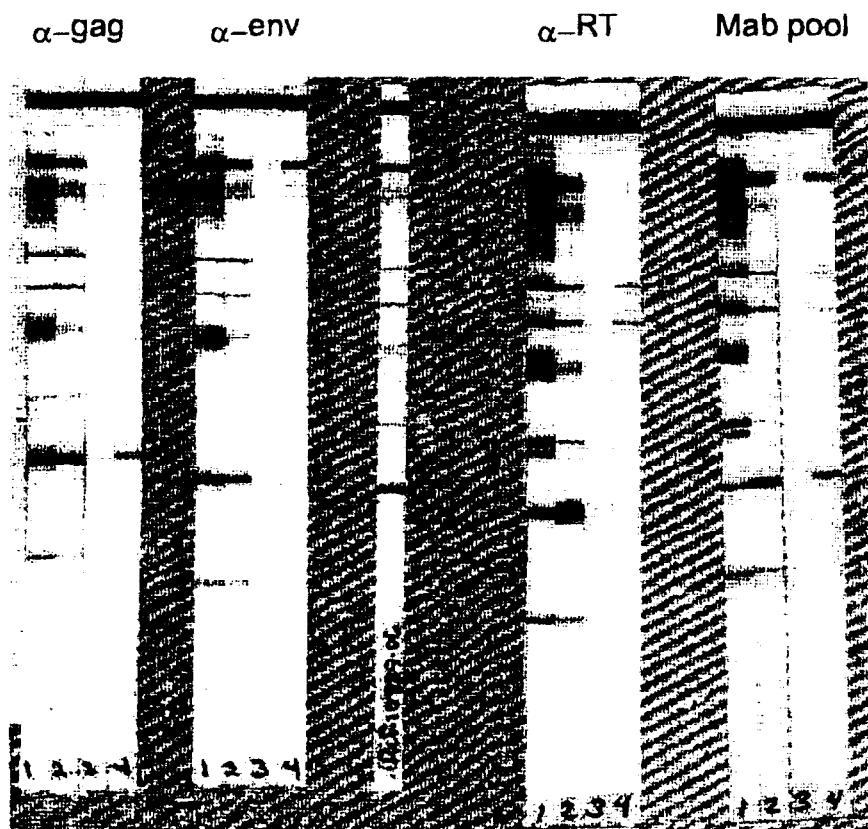
FDA BPAC meeting March 16, 2000
Western blot nonviral bands
Epitope, Inc. Beaverton, OR

Epitope Western Blot Nonviral Bands



FDA BPAC meeting March 16, 2000
Nonviral band indeterminate Western Blots
Epitope, Inc., Beaverton, Oregon

Epitope Western Blot Tested with Monoclonal Antibodies



Strip #1 – High Positive Control
Strip #2 – Low Positive Control
Strip #3 – Negative Control
Strip #4 – Anti-HIV Mab

FDA BPAC meeting March 16, 2000
Western blot nonviral bands
Epitope, Inc. Beaverton, OR

Indeterminate Western Blot References

1. Knuver-Hopf, J., et al., Blood donations indeterminate in HIV-1 western blot analysed by IgM immunoblot and polymerase chain reaction. *Vox Sang.*, 64:89-93; 1993.
2. Ramirez, E., et al., Reactivity patterns and infection status of serum samples with indeterminate western immunoblot tests for antibody to HIV type 1. *J Clin Micro*, 30:4, 801-805; 1992.
3. Healey, D. S., et al., HIV-1 western blot: development and assessment of testing to resolve indeterminate reactivity. *AIDS*, 6:7 629-633; 1992.
4. Dock, N. L. et al., Human immunodeficiency virus infection and indeterminate western blot patterns. *Arch intern med*, 151:525-530; 1991.
5. Jackson, J. B., et al., Absence of HIV infection in blood donors with indeterminate western blot tests for antibody to HIV-1. *NEJM*, 322:4 217-222; 1990.
6. Josephson, S. L., et al., Investigation of atypical western blot (immunoblot) reactivity involving core proteins of human immunodeficiency virus type 1. *J Clin Micro*, 27:5, 932-937; 1989.
7. Kleinman, S., et al., Follow-up testing and notification of anti-HIV western blot atypical (indeterminant) donors. *Transfusion*, 28:3 280-282; 1988.
8. Vardinon, N., et al., Anti-HIV indeterminate western blot in dialysis patients: a long term follow-up. *Am J kid dis*, 33:1, 146-149; 1999.

FDA BPAC meeting March 16, 2000
Western blot nonviral bands
Epitope, Inc. Beaverton, OR